

#### REMARKS/ARGUMENTS

In the Claims, please cancel Claims 16 through 33, and 44 without prejudice. Claims 1, 14 and 34 have been amended in response to the Examiner's rejections. Claim 15 has been amended to address a minor procedural issue. The amendments to Claims 1, 14 and 34 are fully supported by the Application as originally filed on page 3, paragraph 0052, lines 2-6. No new matter has been added.

#### Rejection Under 35 U.S.C. § 102

Claims 1, 4, 6, 8, and 12 are rejected under 35 U.S.C. § 102(b), as being anticipated by US Patent No. 6,029,659 to O'Connor ("O'Connor").

According to the Manual of Patent Examining Procedure ("MPEP") Section 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant respectfully submits that O'Connor does not anticipate any of the Claims of the present invention as set forth herein.

O'Connor discloses an apparatus for dispensing medication wherein canister 11 operates directly on the push button 50 in the same direction as the canister movement to increment counter 40 when the canister 11 is depressed (col. 7, lns 48-51, Figure 5). O'Connor also discloses a back counter wall 718 that attached to the counter by the insertion of triangular tabs into the top counter wall and bottom wall opening (col. 9, lns. 37-40). The Examiner states that O'Connor teaches all of the limitations of the abovementioned claims.

Applicant's invention is directed to an apparatus in which the canister ferrule contacts the switch means for completing an electrical circuit in a direction substantially non-axial to the direction of the canister's movement. (p. 4, paragraph 0063, Figure 8). By contacting the switch means in this manner as

the canister is depressed in the direction of the mouthpiece, for example, the ferrule moves part or all of the way across the switch to complete the dose counter electrical circuit, unimpeded by the switch means as a result of the direction of contact. This provides the most accurate mechanical indication of the valve opening after the electronic dose counter is incremented, (p.6, paragraph 0080), ensuring that the counter is triggered before any medicament is released (p.5, paragraph 0075). Applicant's apparatus is novel in this respect because it truly allows for "over-travel" of the canister over and past the switch means to account for dimensional variations (tolerances) that occur between different mechanical systems, i.e. different canisters (p.5, paragraphs 0074, 0075). Importantly, Figure 21 illustrates how the motion of the canister acting as it moves across the switch permits both switch closure (and therefore dose counting) and valve opening. Applicant's Claims 1 and 34 have been amended to specify that the switch means (or ramp seal) that acts on the switch means permits contact of a ferrule portion of the canister on the switch means (or ramp seal) in a direction substantially non-axial to the direction of the canister's motion.

Contrary to the Applicant's invention, O'Connor's push button is operated directly upon the ferrule, in the axial direction, as the canister is depressed. The canister has a limited range of motion based on the direction of contact with the push button and the length of the push button. As a result, the mechanical differences in canister, the length of the push button, and the placement of the counter module (which ultimately limits depression of the push button because it supports the button itself), may impede the motion of the canister, which may prohibit actual dispensation of the medicament if the valve stem does not move enough for the canister's valve to open. The Applicant's invention accounts for all of these tolerances to permit operation of the counter as well as operation of the valve each time the canister is depressed by a user.

Applicant's invention is also directed to a substantially air and moisture impermeable seal which isolates the counter module from the mouthpiece and canister, both enabling the user to clean the

unit, and preventing contamination from the canister and ambient air (via the mouthpiece) to enter and potentially damage the counter module. (p. 3, paragraph 0052).

Applicant's Claims 1 and 34 have been to specify that the seal is substantially air and moisture impermeable.

O'Connor also discloses merely a back counter wall 718 which helps enclose the counter mechanism. O'Connor provides no disclosure or teaching as to the impermeability of this back counter wall 718.

As a result, the Applicant respectfully submits that O'Connor fails to disclose all of the limitations of Claims 1, 4, 6, 8 and 12 of the present invention and that the Examiner's rejection under 35 U.S.C. 102(b) is moot.

#### Rejections Under 35 U.S.C. § 103

A. Claims 5, 7, 9, 38, 40, and 42 are rejected under 35 U.S.C. § 103 as obvious over US Patent No. 6,029,659 to O'Connor ("O'Connor").

In order to establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *See* MPEP, § 2143.03 ("MPEP"); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580.

As discussed above, the Applicant claims at least two limitations that are not disclosed in O'Connor: (1) contact of the ferrule portion of the canister on the switch means, or ramp seal, in a direction substantially non-axial to the canister's movement, and (2) a seal that is substantially air and moisture impermeable. Claims 5, 7, 9, 38, 40 and 42 depend from Independent Claims 1 and 34, and therefore naturally contain the limitations of those claims from which they depend. As a result, the

Applicant respectfully submits that Claims 5, 7, 9, 38, 40, and 42 are not obvious under § 103(a) in view of O'Connor.

B. The Examiner rejects Claims 10, 11, and 43 under § 103(a) as being unpatentable over O'Connor in view of U.S. Patent No. 6,431,168 to Rand et al. ("Rand"). Rand teaches an apparatus for dispensing medication that includes a switch slide 44 that moves along pin 45 in the same direction as the aerosol container to contact members 46 and 47. Rand's switch directly contacts body 40, which houses the dose counter mechanism, in the axial direction. Rand's design is limited by the mechanical limitations of body 40, the pin 45, and the contact members 46,47. Rand does not disclose or suggest contact of the canister ferrule across the contact member in a direction substantially non-axial to the canister's movement, to allow for "over-travel" of the canister as necessary to dispense the medicament. Therefore, neither O'Connor nor Rand teach the limitations of Independent Claims 1 and 34, and as a result, not all of the limitations of Claims 10, 11, and 43 are taught or suggested by the references. The Applicant respectfully submits that the Examiner's rejections under § 103(a) of these claims are moot.

C. The Examiner rejects Claims 13-15 under § 103(a) as being unpatentable over O'Connor in view of Rand.

Rand discloses contact members 46,47 which define the upper limit of movement on switch slide 44 and which close a circuit when in contact with switch slide 44. Contact members 46,47 do not comprise a "ramp" which is contacted in a direction substantially non-axial to the canister's movement, rather, as the aerosol container moves down, the chamber body 40 accommodating switch slide 44 also moves in the same direction along pin 45 until the switch slide 44 contacts members 46,47 (col. 8, lns. 59-

64). Further, Rand provides no disclosure or teaching that chamber body 40 or support 5 provide any sort of seal to protect against air and/or moisture ingress.

The Applicant's switch means, and ramp, are contacted in a direction substantially non-axial to the canister movement, which, as discussed above, importantly allows for canister over-travel and key mechanical tolerances that must be accounted for. As a result, not all of the limitations of Claims 13-15, which depend from Claim 1, are taught or suggested by the references, and the Applicant respectfully submits that the Examiner's rejection under § 103(a) of Claims 13-15 is moot.



D. The Examiner rejects Claims 16-19 and 22-31 under §103(a) as being unpatentable over O'Connor in view of U.S. Patent No. 5,544,647 to Jewett et al. ("Jewett"). Applicant has cancelled Claims 16-19 and 22-31, rendering the Examiner's rejection moot.

E. The Examiner rejects Claims 20 and 21 under § 103(a) as being unpatentable over O'Connor in view of Jewett and further in view of Rand. Applicant has cancelled Claims 20 and 21, rendering the Examiner's rejection moot.

F. The Examiner rejects Claims 24, 32 and 33 under §103(a) as being unpatentable over O'Connor in view of U.S. Patent 5,363,842 to Mischelevich et al. ("Mischelevich"). Applicant has cancelled Claims 24, 32 and 33, rendering the Examiner's rejection moot.

G. The Examiner rejects Claim 34 under §103(a) as being unpatentable over O'Connor in view of Rand. As discussed above, O'Connor does not disclose all of the limitations of this Claim. Also, Rand's contact members 46/47 do not comprise a "ramp". Contact members 46/47 do not move in a direction

substantially non-axial to the plane of the canister movement to close the electrical circuit. As a result, these references do not teach or suggest all of the limitations of the Claim. Therefore, Applicant respectfully submits that the Examiner's rejection of Claim 34 under § 103(a) is moot.

H. The Examiner rejects Claims 35-37, 39, 41, and 44-54 under §103(a) as being unpatentable over O'Connor. Applicant has cancelled Claim 44. In view of the Applicant's amendments to Claim 34 as discussed above, the Applicant respectfully submits that O'Connor fails to teach or suggest all of the limitations of Claims 35-37, 39, 41 and 45-54, which depend from Claim 34. As a result, the Applicant respectfully submits that the Examiner's rejections are moot.

Based on the amendments and remarks set forth above, the Applicant hereby respectfully requests that the Examiner's rejections be withdrawn and that the Application is in condition for allowance. Should the Examiner have questions or require additional information or clarification, please do not hesitate to contact the Applicant's undersigned attorney. Please charge any required fees to our Deposit Account No. 50-2543.

Respectfully submitted,

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